General

Guideline Title

Evidence-based guideline: assessment and management of psychiatric disorders in individuals with MS. Report of the Guideline Development Subcommittee of the American Academy of Neurology.

Bibliographic Source(s)

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Definitions of the levels of the recommendations (A, B, C, U) and classification of the evidence (Class I-IV) are provided at the end of the "Major Recommendations" field.

<u>Screening and Diagnosis</u>

What Clinical Evaluation Procedures and Screening and Diagnostic Tools Can Be Used to Accurately Identify Symptoms and Make Diagnoses of Emotional Disorders in Individuals with Multiple Sclerosis (MS)?

Conclusions and Recommendations

In individuals with MS, the Center for Neurologic Study Emotional Lability Scale (CNS-LS) is possibly effective and may be considered for screening for pseudobulbar affect (PBA) (Level C, 1 Class II study [Smith et al., 2004]). The General Health Questionnaire (GHQ) (Goldberg & Hillier, 1979) is possibly effective and may be considered for identifying individuals with broadly defined emotional disturbances (Level C, 1 Class II study [Rabins & Brooks, 1981]). The Beck Depression Inventory (BDI) (Beck et al., 1961) and a 2-question screen (Whooley et al., 1997) are possibly effective and may be considered for identifying individuals with major depressive disorder (MDD) (Level C, 1 Class II study each [Sullivan et al., 1995; Mohr et al., 2007]). There is insufficient evidence to support/refute using the Center for Epidemiologic Studies Depression Rating Scale (CES-D) (Radloff, 1977) to screen for depressive symptoms (Pandya, Metz, & Patten, 2005) or a single question to screen for MDD (Vahter et al., 2007) (Level U, 1 Class III study each); the possibility that somatic or neurovegetative symptoms negatively affect the accuracy of BDI results (Level U, 2 conflicting Class III studies) (Mohr et al., 1997; Randolph et al., 2000); and the use of specific instruments or clinical evaluation procedures to diagnose emotional disorders in individuals with MS (Level U).

Clinical Context

Because emotional disorders may be unrecognized in medical settings, validated screening tools might improve identification of individuals who could benefit from further evaluation and treatment. The true positive rate of a screening tool depends not only on its sensitivity but also on the point prevalence of the disorder in the population under study. Clinically, false-positive results are not a major concern because individuals with the conditions typically identified (e.g., adjustment and subthreshold depressive disorders) can benefit from further assessment. Administratively, however, screening tools with high false-positive rates unnecessarily increase resource use.

<u>Treatments</u>

What Are the Effective Treatments for Disorders of Mood in Individuals with MS?

Conclusion and Recommendations

For individuals with MS, a 16-week program of individual telephone-administered cognitive behavioral therapy (T-CBT) program is possibly effective and may be considered in treating depressive symptoms (Level C, 1 Class II study [Mohr et al., 2005], 1 Class III study [Mohr, et al., 2000]). There is insufficient evidence to support/refute the efficacy and use of 1) sertraline (Mohr et al., 2001), desipramine (Schiffer & Wineman, 1990), paroxetine (Ehde et al., 2008), individual in-person cognitive behavioral therapy (CBT) (Mohr et al., 2001), individual in-person CBT plus relaxation training (Foley et al., 1987), or CBT-based group therapy (Forman & Lincoln, 2010) for depressive symptoms; or 2) individual in-person CBT plus relaxation training (Foley et al., 1987), group relaxation and imagery (Maguire, 1996), or CBT-based group therapy (Forman & Lincoln, 2010) for anxiety (Level U, 1 Class III study each).

Clinical Context

There is evidence supporting the efficacy of pharmacologic and nonpharmacologic therapies for depressed mood and anxiety in individuals without MS. Despite the lack of evidence in individuals with MS, these therapies are frequently used to treat emotional disorders in this population.

What Are the Effective Treatments for Disorders of Affect in Individuals with MS?

Conclusion and Recommendations

Dextromethorphan and quinidine (DM/Q) is possibly effective and safe and may be considered for treating individuals with MS with PBA (Level C, 1 Class II study) (Panitch et al., 2006).

Clinical Context

DM/Q is the only drug approved by the US Food and Drug Administration for PBA treatment, although other drugs are used in clinical practice (e.g., selective serotonin reuptake inhibitors, tricyclic antidepressants). There are no randomized placebo-controlled trials of these other agents.

<u>Definitions:</u>

<u>Classification of Evidence</u>

Screening Articles

Class I: A statistical, population based sample of patients studied at a uniform point in time (usually early) during the course of the condition. All patients undergo the intervention of interest. The outcome, if not objective, is determined in an evaluation that is masked to the patients' clinical presentations.

Class II: A statistical, non-referral clinic based sample of patients studied at a uniform point in time (usually early) during the course of the condition. Most patients undergo the intervention of interest. The outcome, if not objective, is determined in an evaluation that is masked to the patients' clinical presentations.

Class III: A sample of patients studied during the course of the condition. Some patients undergo the intervention of interest. The outcome, if not objective, is determined in an evaluation by someone other than the treating physician.

Class IV: Studies not meeting Class I, II, or III criteria, including consensus, expert opinion or a case report.

Diagnostic Articles

Class I: A cohort study with prospective data collection of a broad spectrum of persons with the suspected condition, using an acceptable

reference standard for case definition. The diagnostic test is objective or performed and interpreted without knowledge of the patient's clinical status. Study results allow calculation of measures of diagnostic accuracy.

Class II: A case control study of a broad spectrum of persons with the condition established by an acceptable reference standard compared to a broad spectrum of controls or a cohort study where a broad spectrum of persons with the suspected condition where the data was collected retrospectively. The diagnostic test is objective or performed and interpreted without knowledge of disease status. Study results allow calculation of measures of diagnostic accuracy.

Class III: A case control study or cohort study where either persons with the condition or controls are of a narrow spectrum. The condition is established by an acceptable reference standard. The reference standard and diagnostic test are objective or performed and interpreted by different observers. Study results allow calculation of measures of diagnostic accuracy.

Class IV: Studies not meeting Class I, II, or III criteria including consensus, expert opinion, or a case report.

Therapeutic Articles

Class I: A randomized, controlled clinical trial of the intervention of interest with masked or objective outcome assessment, in a representative population. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

The following are also required:

a. Concealed allocation
b. Primary outcome(s) clearly defined
c. Exclusion/inclusion criteria clearly defined
d. Adequate accounting for dropouts (with at least 80% of enrolled subjects completing the study) and crossovers with numbers sufficiently low to have minimal potential for bias.
e. For noninferiority or equivalence trials claiming to prove efficacy for one or both drugs, the following are also required*:
    1. The authors explicitly state the clinically meaningful difference to be excluded by defining the threshold for equivalence or noninferiority.
    2. The standard treatment used in the study is substantially similar to that used in previous studies establishing efficacy of the standard treatment (e.g., for a drug, the mode of administration, dose and dosage adjustments are similar to those previously shown to be effective).
    3. The inclusion and exclusion criteria for patient selection and the outcomes of patients on the standard treatment are comparable to those of previous studies establishing efficacy of the standard treatment.
    4. The interpretation of the results of the study is based upon a per protocol analysis that takes into account dropouts or crossovers.

Class II: A randomized controlled clinical trial of the intervention of interest in a representative population with masked or objective outcome assessment that lacks one criteria a–e above or a prospective matched cohort study with masked or objective outcome assessment in a representative population that meets b–e above. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.**

Class IV: Studies not meeting Class I, II, or III criteria including consensus or expert opinion.

*Note that numbers 1-3 in Class Ie are required for Class II in equivalence trials. If any one of the three is missing, the class is automatically downgraded to Class III.

**Objective outcome measurement: an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).

Classification of Recommendations

Level A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)*

Level B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

Level C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

Level U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

* In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Multiple sclerosis (MS) and psychiatric disorders, including:

- Pseudobulbar affect (PBA)
- Major depressive disorder (MDD)
- Bipolar disorder
- Anxiety disorder
- Psychotic disorders

Guideline Category

Diagnosis

Evaluation

Management

Screening

Treatment

Clinical Specialty

Family Practice

Neurology

Psychiatry

Psychology

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Guideline Objective(s)

To make evidence-based recommendations for screening, diagnosing, and treating psychiatric disorders in individuals with multiple sclerosis (MS)

Target Population

Individuals with multiple sclerosis (MS) and possible emotional disorders

Interventions and Practices Considered

Screening/Diagnosis

Screening tools, including:

- Center for Neurologic Study Emotional Lability Scale (CNS-LS)
- General Health Questionnaire (GHQ)
- Beck Depression Inventory (BDI)
- 2-question screen

Treatment

1. Telephone-administered cognitive behavioral therapy program (T-CBT)
2. Pharmacologic therapy (dextromethorphan and quinidine [DM/Q])

Note: The following interventions were considered but there was insufficient evidence to be recommended:

> Center for Epidemiologic Studies Depression Rating Scale (CES-D)
> Nonpharmacologic therapy, including individual and group therapies
> Antidepressants

Major Outcomes Considered

- Suicide
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

In February 2007, the authors searched the MEDLINE, EMBASE, CINAHL, Web of Science, and Cochrane databases in all languages, using the MeSH term and its text word synonyms and key words for the topics addressed by the clinical questions (see Appendix e-3 of the data supplement for search strategy and terms [see the "Availability of Companion Documents" field]). A total of 4,540 citations were retrieved. The authors updated the search in August 2011 and identified 605 additional citations, making a combined total of 5,145 citations. At least 2 authors reviewed all 5,145 abstracts. The review yielded 953 articles to be submitted to full-text review.

Number of Source Documents

115 documents were systematically reviewed and rated.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

<u>Classification of Evidence</u>

Screening Articles

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Class IV: Studies not meeting Class I, II, or III criteria, including consensus, expert opinion or a case report.

Diagnostic Articles

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Class II: A case control study of a broad spectrum of persons with the condition established by an acceptable reference standard compared to a broad spectrum of controls or a cohort study where a broad spectrum of persons with the suspected condition where the data was collected retrospectively. The diagnostic test is objective or performed and interpreted without knowledge of disease status. Study results allow calculation of measures of diagnostic accuracy.

Class III: A case control study or cohort study where either persons with the condition or controls are of a narrow spectrum. The condition is established by an acceptable reference standard. The reference standard and diagnostic test are objective or performed and interpreted by different observers. Study results allow calculation of measures of diagnostic accuracy.

Class IV: Studies not meeting Class I, II, or III criteria including consensus, expert opinion, or a case report.

Therapeutic Articles

Class I: A randomized, controlled clinical trial of the intervention of interest with masked or objective outcome assessment, in a representative population. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences. The following are also required:

a. Concealed allocation
b. Primary outcome(s) clearly defined
c. Exclusion/inclusion criteria clearly defined
d. Adequate accounting for dropouts (with at least 80% of enrolled subjects completing the study) and crossovers with numbers sufficiently low to have minimal potential for bias.
e. For noninferiority or equivalence trials claiming to prove efficacy for one or both drugs, the following are also required*:
   1. The authors explicitly state the clinically meaningful difference to be excluded by defining the threshold for equivalence or noninferiority.

2. The standard treatment used in the study is substantially similar to that used in previous studies establishing efficacy of the standard treatment (e.g., for a drug, the mode of administration, dose and dosage adjustments are similar to those previously shown to be effective).
3. The inclusion and exclusion criteria for patient selection and the outcomes of patients on the standard treatment are comparable to those of previous studies establishing efficacy of the standard treatment.
4. The interpretation of the results of the study is based upon a per-protocol analysis that takes into account dropouts or crossovers.

Class II: A randomized controlled clinical trial of the intervention of interest in a representative population with masked or objective outcome assessment that lacks one criteria a–e above or a prospective matched cohort study with masked or objective outcome assessment in a representative population that meets b–e above. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.**

Class IV: Studies not meeting Class I, II, or III criteria including consensus or expert opinion.

*Note that numbers 1-3 in Class Ie are required for Class II in equivalence trials. If any one of the three is missing, the class is automatically downgraded to Class III.

**Objective outcome measurement: an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Of the 953 articles identified in the literature search, 115 were determined to have data relating to one or more of the clinical questions. These were reviewed and classified according to American Academy of Neurology (AAN) criteria for screening, diagnostic, and therapeutic studies (see Appendix e-4 of the data supplement [see the "Availability of Companion Documents" field]), resulting in 41 Class I–III studies combined for both searches. The recommendations were linked to the strength of evidence (see Appendix e-5 in the data supplement) and intervention effect size. A third reviewer arbitrated discrepant classifications. The authors excluded case reports, review papers, studies with fewer than 20 subjects, and therapeutic studies that did not specify the psychiatric disorder being treated or report scores on both pre- and posttreatment symptom severity measures. Several articles with prevalence data were evaluated but not cited in the manuscript. These are listed in Appendix e-6 in the data supplement.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

In November 2006, the American Academy of Neurology Guideline Development Subcommittee convened a panel from North America representing a broad range of relevant expertise, including specialists in psychiatry, psychology, neurology, multiple sclerosis (MS), and guideline development methodology.

The project development plan had 9 clinical questions. The authors found evidence to support recommendations for the 3 listed below:

1. What clinical evaluation procedures and screening and diagnostic tools can be used to accurately identify symptoms and make diagnoses of emotional disorders in individuals with MS?
2. What are the effective treatments for disorders of mood in individuals with MS?
3. What are the effective treatments for disorders of affect in individuals with MS?

Rating Scheme for the Strength of the Recommendations

Classification of Recommendations

Level A = Established as effective, ineffective or harmful (or established as useful/predictive or not useful/predictive) for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)*

Level B = Probably effective, ineffective or harmful (or probably useful/predictive or not useful/predictive) for the given condition in the specified population. (Level B rating requires at least one Class I study or two consistent Class II studies.)

Level C = Possibly effective, ineffective or harmful (or possibly useful/predictive or not useful/predictive) for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

Level U = Data inadequate or conflicting; given current knowledge, treatment (test, predictor) is unproven.

* In exceptional cases, one convincing Class I study may suffice for an "A" recommendation if 1) all criteria are met, 2) the magnitude of effect is large (relative rate improved outcome >5 and the lower limit of the confidence interval is >2).

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Drafts of the guideline have been reviewed by at least 3 American Academy of Neurology (AAN) committees, a network of neurologists, *Neurology*® peer reviewers, and representatives from related fields.

The guideline was approved by the Guideline Development Subcommittee on January 12, 2013; by the Practice Committee on February 17, 2013; and by the AAN Board of Directors on October 2, 2013.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Beck AT, Ward CH, Mendelson M, Mock J, Erbaugh J. An inventory for measuring depression. Arch Gen Psychiatry. 1961 Jun;4:561-71.

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Sullivan MJ, Weinshenker B, Mikail S, Bishop SR. Screening for major depression in the early stages of multiple sclerosis. Can J Neurol Sci.

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Whooley MA, Avins AL, Miranda J, Browner WS. Case-finding instruments for depression. Two questions are as good as many. J Gen Intern Med. 1997 Jul;12(7):439-45. PubMed

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate assessment and management of psychiatric disorders in individuals with multiple sclerosis (MS)

Potential Harms

- Clinically, false-positive results are not a major concern because individuals with the conditions typically identified (e.g., adjustment and subthreshold depressive disorders) can benefit from further assessment. Administratively, screening tools with high false positive rates unnecessarily increase resource use.
- In a randomized controlled trial comparing dextromethorphan and quinidine (DM/Q) with placebo, dizziness was the only adverse event that occurred more frequently in the treated (26.3%) vs placebo (9.5%) group, and only one treated subject rated it as severe.

Qualifying Statements

Qualifying Statements

This statement is provided as an educational service of the American Academy of Neurology (AAN). It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved. The clinical context section is made available in order to place the evidence-based guideline(s) into perspective with current practice habits and challenges. Formal practice recommendations are not intended to replace clinical judgment.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

Quick Reference Guides/Physician Guides

Resources

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Minden SL, Feinstein A, Kalb RC, Miller D, Mohr DC, Patten SB, Bever C Jr, Schiffer RB, Gronseth GS, Narayanaswami P. Evidence-based guideline: assessment and management of psychiatric disorders in individuals with MS. Report of the Guideline Development Subcommittee of the American Academy of Neurology. Neurology. 2014 Jan 14;82(2):174-81. [40 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Jan 14

Guideline Developer(s)

American Academy of Neurology - Medical Specialty Society

Source(s) of Funding

This evidence-based guideline was funded by the American Academy of Neurology. No author received honoraria or financial support to develop this document.

Guideline Committee

Guideline Development Subcommittee of the American Academy of Neurology

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Conflict of Interest

The American Academy of Neurology (AAN) is committed to producing independent, critical, and truthful clinical practice guidelines (CPGs). Significant efforts are made to minimize the potential for conflicts of interest to influence the recommendations of this CPG. To the extent possible, the AAN keeps separate those who have a financial stake in the success or failure of the products appraised in the CPGs and the developers of the guidelines. Conflict of interest forms were obtained from all authors and reviewed by an oversight committee prior to project initiation. AAN limits the participation of authors with substantial conflicts of interest. The AAN forbids commercial participation in, or funding of, guideline projects.

Disclosures

S. Minden has received honoraria and travel reimbursement for meetings on mood and cognition in multiple sclerosis (MS) from Pfizer, Merck-Serono, and Genentech; on fingolimod from Novartis; and on dextromethorphan and quinidine from Avanir; has received research support from the National Multiple Sclerosis Society (NMSS), the Center for Mental Health Services, and the Substance Abuse and Mental Health Services Administration; and has stock in Merck, Schering-Plough, and SmithKline.

A. Feinstein has received travel funding from Merck-Serono, Teva, and Bayer; is serving as a member of an editorial advisory board for MS; has received publishing royalties from the Clinical Neuropsychiatry of Multiple Sclerosis (Cambridge University Press), Journalists Under Fire (John Hopkins University Press), and Michael Rabin: America's Virtuoso Violinist (Amadeus Press); and has received honoraria from Merck-Serono, Bayer, Teva, and Biogen.

R. Kalb has received publishing royalties from Demos Medical Publishing and Wiley Publishing, and has received honoraria for Can Do Multiple Sclerosis.

D. Miller is serving as a journal editor, associate editor, or member of an editorial advisory board for Journal of Rehabilitation Research & Development; and has received financial or material research support or compensation from Novartis and the NMSS.

D. Mohr has received research support from the NIH.

S. Patten is a member of the editorial board of the Canadian Journal of Psychiatry, and has received research support from the Government of Alberta's Collaborative Research Grant Initiative, the Canadian Institutes for Health Research, and the Institute of Health Economics.

C. Bever received travel funding from the American Academy of Neurology (AAN), the University of Maryland School of Medicine, and the Department of Veterans Affairs; has a patent held or pending for use of hematogenous stem cells in neuronal replacement therapy and gene delivery; has received funding for merit grants from the Department of Veterans Affairs and a pilot grant from the NMSS; and has received license fee payments and royalty payments (or has contractual rights for receipt of future royalty payments) related to the patent disclosed above.

Dr. Bever's spouse has received publishing royalties from Ambulatory Medicine, Barker et al.

R. Schiffer, G. Gronseth, and P. Narayanaswami have no relevant disclosures to report.

Go to Neurology.org [_____] for full disclosures.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: American Academy of Neurology (AAN) guidelines, along with a link to a Portable Document Format (PDF) file for this guideline, are available at the AAN Web site [_____].

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 201 Chicago Avenue South, Minneapolis, MN 55415.

Availability of Companion Documents

The following are available:

- Evidence-based guideline: assessment and management of psychiatric disorders in individuals with MS. Data supplement (e-appendices, e-references, e-tables). St. Paul (MN): American Academy of Neurology; 2014. Electronic copies: Available from the Neurology Journal Web site [_____].
- Evidence-based guideline: assessment and management of psychiatric disorders in individuals with MS. AAN summary of evidence-based guideline for clinicians. St. Paul (MN): American Academy of Neurology; 2013. 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American Academy of Neurology (AAN) Web site [_____].
- Evidence-based guideline: assessment and management of psychiatric disorders in individuals with MS. Podcast. St. Paul (MN): American Academy of Neurology; 2014. Available from the Neurology Journal Web site [_____].
- AAN guideline development process [online]. St. Paul (MN): American Academy of Neurology. Available from the AAN Web site [_____].

Patient Resources

The following is available:

- Emotional disorders in people with multiple sclerosis. Summary of evidence-based guideline for patients and their families. St. Paul (MN): American Academy of Neurology. 2013. 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American Academy of Neurology (AAN) Web site [_____].

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